

What is claimed is:

1. A clinical research data management system for a plurality of users comprising:
a computer system operable to service user requests and provide users with information responsive to the user requests, and
a database coupled to the computer system, wherein the database is operable to store user data and study data and wherein the study data includes candidate data, specimen data, event data and at least one dataset and wherein the dataset is defined using metadata.
2. The system of claim 1 wherein the database is operable to store data related to scheduled events and unscheduled events.
3. The system of claim 1 wherein the computer system is operable to send and receive electronic messages between at least two users.
4. The system of claim 3 wherein the computer system is operable to limit communication of electronic messages between users having a specific role in connection with a specific study.
5. The system of claim 1 wherein the candidate data includes data relating to a plurality of candidates and the specimen data includes data relating to a plurality of specimens wherein the system is operable to associate each specimen with a candidate.
6. The system of claim 1 wherein the user data includes at least one role associated with each user.
7. The system of claim 1 wherein the user data includes at least one role associated with each user, wherein the role is selected from the group of data monitor, enroller, data editor, study administrator and system administrator.

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8. The system of claim 6 wherein the role defines data access rights granted at a dataset definition level.
9. The system of claim 6 wherein the role defines data access rights granted at a data item definition level.
10. The system of claim 6 wherein the role defines data access rights granted at a dataset definition level and data item definition level.
11. The system of claim 6 wherein the database is operable to identify at least a portion of the user data as privacy data and wherein the role defines a users ability to view privacy data.
12. The system of claim 1 wherein the database includes at least one display form associated with the dataset and wherein the display form is defined using metadata.
13. The system of claim 1 wherein the database includes at least two display forms associated with the dataset and wherein the display forms are defined using metadata.
14. The system of claim 13 wherein a first display form is formatted to render the dataset on a first display device, and a second display form is formatted to render the dataset on a second display device.
15. The system of claim 13 wherein a first display form is formatted to render the dataset in a first language, and a second display form is formatted to render the dataset in a second language.
16. The system of claim 1 wherein the database stores an audit record of data access including information relating to the data accessed, user, date and time.
17. The system of claim 1 wherein at least a portion of the user data or study data is stored in the database in an encrypted format.

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18. A clinical research data management method for a plurality of users comprising:
storing user data and study data in a database coupled to a computer system,
wherein the study data includes candidate data, specimen data, event data and at least one
dataset and wherein the dataset is defined using metadata.
19. The method of claim 18 wherein the database is operable to store data related to
scheduled events and unscheduled events.
20. The method of claim 18 wherein the computer system is operable to send and
receive electronic messages between at least two users.
21. The method of claim 20 wherein the computer system is operable to limit
communication of electronic messages between users having a specific role in
connection with a specific study.
22. The method of claim 18 wherein the candidate data includes data relating to a
plurality of candidates and the specimen data includes data relating to a plurality of
specimens wherein the system is operable to associate each specimen with a candidate.
23. The method of claim 18 wherein the user data includes at least one role
associated with each user.
24. The method of claim 18 wherein the user data includes at least one role
associated with each user, wherein the role is selected from the group of data monitor,
enroller, data editor, study administrator and system administrator.
25. The method of claim 23 wherein the role defines data access rights granted at a
dataset definition level.
26. The method of claim 23 wherein the role defines data access rights granted at a
data item definition level.

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27. The method of claim 23 wherein the role defines data access rights granted at a dataset definition level and data item definition level.
28. The method of claim 23 wherein the database is operable to identify at least a portion of the user data as privacy data and wherein the role defines a users ability to view privacy data.
29. The method of claim 18 wherein the database includes at least one display form associated with the dataset and wherein the display form is defined using metadata.
30. The method of claim 18 wherein the database includes at least two display forms associated with the dataset and wherein the display forms are defined using metadata.
31. The method of claim 18 wherein a first display form is formatted to render the dataset on a first display device, and a second display form is formatted to render the dataset on a second display device.
32. The method of claim 18 wherein a first display form is formatted to render the dataset in a first language, and a second display form is formatted to render the dataset in a second language.
33. The method of claim 18 wherein the database stores an audit record of data access including information relating to the data accessed, user, date and time.
34. A clinical research data management system for a plurality of users comprising:
a computer system operable to service user requests and provide users with information responsive to the user requests, and
a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies, wherein study data includes candidate data, specimen data, event data and at least one dataset, wherein user data includes at least one role associated with each user and wherein the role defines data access rights granted at one of a dataset definition level and data item definition level.

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35. A clinical research data management system for a plurality of users comprising:
a computer system operable to service user requests and provide users with information responsive to the user requests, and
a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies, wherein study data includes candidate data, specimen data, event data and at least one dataset, wherein user data includes at least one role associated with each user and wherein the computer system is operable to limit communication of electronic messages between user having a specific role in connection with a specific study.
36. A clinical research data management system for a plurality of users comprising:
a means for servicing user requests and providing users with information responsive to the user requests, and
a database for storing user data and study data and wherein the study data includes candidate data, specimen data, event data and at least one dataset and wherein the dataset is defined using metadata.
37. A clinical research data management system for administering a plurality of studies, the system having a computer system operable to service user requests and provide users with information responsive to the user requests and a database with a flexible database structure that facilitates the study definition process for a broad range of studies, the system comprising:
(a) presentation creation means operable to provide users with dynamic information,
(b) application control and navigation means operable to service user requests,
(c) data access means operable to access information that resides in a system database wherein the database is operable to store user data and study data and wherein the study data includes candidate data, specimen data, event data and at least one dataset and wherein the dataset is defined using metadata.
38. The system of claim 37 further comprising:
(d) application and data security means operable to limit users access to information in the system database.

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